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| APPLICATION NO.                                                   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|-------------------------------------------------------------------|-------------|----------------------|----------------------|------------------|
| 10/820,277                                                        | 04/08/2004  | Kimberly O. Cameron  | PC10041C             | 8609             |
| 28880                                                             | 7590        | 02/25/2005           | EXAMINER             |                  |
| WARNER-LAMBERT COMPANY<br>2800 PLYMOUTH RD<br>ANN ARBOR, MI 48105 |             |                      | SEAMAN, D MARGARET M |                  |
|                                                                   |             |                      | ART UNIT             | PAPER NUMBER     |
|                                                                   |             |                      | 1625                 |                  |

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

|                    |                  |  |
|--------------------|------------------|--|
| Application No.    | 10/820,277       |  |
| Examiner           | CAMERON ET AL.   |  |
| D. Margaret Seaman | Art Unit<br>1625 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-75 are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

## DETAILED ACTION

This application was filed 4/8/2004 and is a ~~P~~CON of 10/405308 (filed 4/2/2003, ABN) which is a DIV of 09/745396 (filed 12/21/2000, US Patent #6,608,203) which claims benefit of Provisional Application 60/173063 (12/24/1999). Claims 1-75 are before the Examiner.

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-44 and 65-66, drawn to compounds and a composition, classified in class 546, subclass 153+.
  - II. Claims 45-48, drawn to method for treating by mediation of an estrogen receptor, classified in class 514, subclass 312+.
  - III. Claims 49-52 and 67, drawn to method of treating using compounds plus an anabolic agent, classified in class 514, subclass 1+.
  - IV. Claims 53-56 and 68, drawn to method of treating using compounds plus a growth hormone, classified in class 514, subclass 1+.
  - V. Claims 57-60 and 69, drawn to method of treating using compounds plus a prostaglandin agonist, classified in class 514, subclass 1+.
  - VI. Claims 61-64 and 70, drawn to method of treating using compounds plus a parathyroid hormone, classified in class 514, subclass 1+.
  - VII. Claim 71, drawn to a kit of the compound alone, classified in class 514, subclass 1+.

VIII. Claim 72, drawn to a kit of the compound plus an anabolic agent, classified in class 514, subclass 1+.

IX. Claim 73, drawn to a kit of the compound and a growth hormone, classified in class 514, subclass 1+.

X. Claim 74, drawn to a kit of the compound and a prostaglandin agonist/antagonist, classified in class 514, subclass 1+.

XI. Claim 75, drawn to a kit of the compound and a parathyroid hormone, classified in class 514, subclass 1+.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and III-VI as well as VII and VIII-XI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the group II is drawn to the method of treating using the compound alone and the groups III-VI have other active ingredients that could treat other conditions/disease states that the compound alone does not treat. Also, in the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the group VII

having a kit with the compound alone does not have the same indication as the groups VIII-XI being the kit of the compound plus another active ingredient. The other active ingredients can treat other disease/conditions that the instant compound cannot treat.

3. Inventions I and II-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to treat conditions that the further process of use groups II-VI cannot and the groups II-VI can be used to treat conditions that the compounds of group I cannot.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. A telephone call was made to Michael Dixon on 2/22/2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Margaret Seaman  
Primary Examiner  
Art Unit 1625

dms